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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,355	12/29/2000	William F. Polley	56301P551	9724

8791 7590 11/19/2002

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EXAMINER

FLYNN, AMANDA R

ART UNIT	PAPER NUMBER
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3751

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/753,355

Applicant(s)

POLLEY ET AL.

Examiner

Amanda R. Flynn

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- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Invention II in Paper No. 6 is acknowledged.
2. Claims 1-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 6.

Drawings

3. Formal drawings submitted by the Applicant have been entered into the file as Paper No. 4, and are acknowledged by the Examiner.

Specification

4. The abstract of the disclosure is objected to because its length falls less than the required 50 to 150 words and does not adequately describe the invention. Correction is required. See MPEP § 608.01(b).
5. The disclosure is objected to because of the following informalities: On line 13 of page 1, the tense of the word "press" should be corrected to --pressed--.

Appropriate correction is required.

6. The use of the trademark CFLEX and KRATON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

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7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification lacks antecedent basis for the particular shapes of the finger tab portion (rectangular, cylindrical, spherical or square).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 19, 24 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19, 24 and 30 fail to list the potential shapes of the finger tab portion in the alternative, therefore rendering the claims indefinite. Substitution of the word --or-- in place of the word "and" would resolve this rejection.

10. Claims 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitations "the first finger tab and" and "the second finger tab" in line 3. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 16 and 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,188,605 to Sleep.

Sleep discloses an introducer comprising a circular finger tab portion 54, a tube portion 40 and a hinge portion 60, placed between the finger tab and tube portions, forming a "seamless" introducer. Sleep states that the tube portion is substantially hollow, having a diameter sufficient to accommodate a balloon catheter. (col. 3, lines 47-51) Further, Sleep discloses a scoreline, or a "line of weakness" 52, along the tube portion of the introducer.

13. Claims 25 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,167,634 to Corrigan, Jr. et al.

Corrigan, Jr. et al. disclose an introducer comprising a substantially hollow tube 18, first and second rectangular finger tab portions 14 that are formed at the proximal end of the tube "without seams," and a scoreline 26 formed along the tube. Corrigan, Jr. et al. disclose that the scoreline extends to a beveled and tapered portion 25 at the distal tip of the introducer.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sleep in view of U.S. Patent Number 5,263,938 to Orr et al.

Sleep discloses the previously described introducer (paragraph 11), but does not disclose that the introducer is made of polycarbonate.

Orr et al. disclose an introducer assembly that is made of polycarbonate, for its “semi-rigid” properties. (col. 3, lines 34-37)

It would have been obvious to one skilled in the art at the time the invention was made to have provided the introducer as disclosed by Sleep, with a polycarbonate material as taught by Orr et al., to improve the semi-rigid properties of the device.

16. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corrigan, Jr. et al. in view of U.S. Patent Number 5,782,817 to Franzel et al.

Corrigan, Jr. et al. disclose the previously described introducer (paragraph 12), but do not disclose a safety valve coupled to the proximal end of the introducer.

Franzel et al. disclose an introducer with a toroidal safety valve 18 on the proximal end of the introducer, to prevent backflow of blood. (col. 2, lines 58-60)

It would have been obvious to one skilled in the art at the time the invention was made to have provided the introducer as disclosed by Corrigan, Jr. et al, with a safety valve as taught by Franzel et al., to prevent backflow of blood during use.

17. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corrigan, Jr. et al, in view of Orr et al.

Corrigan, Jr. et al. disclose the previously described introducer (paragraph 12), but do not disclose that the introducer is made of polycarbonate.

Orr et al. disclose an introducer assembly that is made of polycarbonate, for its “semi-rigid” properties. (col. 3, lines 34-37)

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It would have been obvious to one skilled in the art at the time the invention was made to have provided the introducer as disclosed by Corrigan, Jr. et al., with a polycarbonate material as taught by Orr et al., to improve the semi-rigid properties of the device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda R. Flynn whose telephone number is 703-306-4056. The examiner can normally be reached on Monday-Thursday, 8:00 - 5:30 and alternate Fridays.

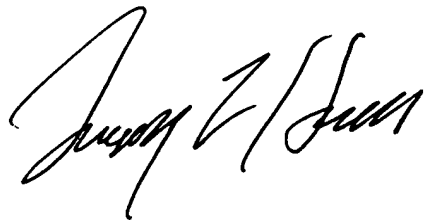
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory L. Huson can be reached on 703-308-2580. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

Amanda R. Flynn
Examiner
Art Unit 3751

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November 13, 2002

 11/13/02

GREGORY HUSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700